REMARKS

Claims 15, 24 and 35 were amended to correct the typographical errors wherein the inverted A should be alpha (α). Support for these amendments can be found in the priority document U.S. Serial No. 60/399,192.

The specification was also amended to correct the typographical errors wherein the inverted A should be alpha (α) and the reversed E should be a beta (β). Support for the amendments to the specification on pages 7, 14 and 19 can be found in the priority document U.S. Serial No. 60/399,192.

Support for the amendment to the specification on page 9, line 3, can be found at least at page 21, lines 15-20 and Figure 1 as originally filed.

Support for the amendment to the specification on page 25, can be found at least at Figure 6 as originally filed and in the priority document U.S. Serial No. 60/399,192.

No new matter is entered by way of these amendments.

Restriction Requirement

Although Applicants did not traverse the restriction requirement, Applicants do not concede that the claims fail to comprise a special technical feature over U.S. Patent No. 6,673,606 to Tennekoon. Tennekoon does not anticipate the present claims, and the claims comprise a special technical feature over the prior art at least for the reasons described below.

35 U.S.C. § 102

Claims 1-2, 5, 12-15 and 17-18 were rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Patent No. 6,673,606 to Tennekoon et al., ("Tennekoon").

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and every element of the claims. *Hybritech Inc. v Monoclonal Antibodies Inc.*, 231 USPQ 81 (Fed. Cir. 1986); *Scripps Clinic & Research Found. v Genentech Inc.*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*:

> Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . There must be no difference

> between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

A reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. As the Federal Circuit held in *Scripps*:

> [A] finding of anticipation requires that all aspects of the claimed invention were already described in a single reference: a finding that is not supportable if it is necessary to prove facts beyond those disclosed in the reference in order to meet the claim limitations. The role of extrinsic evidence is to educate the decision-maker to what the reference meant to persons of ordinary skill in the field of the invention, not to fill in the gaps in the reference.

The cited passages of Tennekoon do not disclose or suggest the claimed methods. The Examiner argues that a cell that can differentiate into oligodendrocytes and neurons is inherently a multipotent neural stem cell. However, Tennekoon states at column 1, line 66 to column 2, line 2, that "[i]t is therefore an object of the present invention to provide a source for differentiated oligodendrocytes and neurons, respectively, that is *independent of neural stem cells* and conventional cell lines." Therefore, Tennekoon's mesenchymal stromal cells are not and do not include neural stem cells. Tennekoon also states that neural stem cells have drawbacks and are difficult to obtain (see column 1, lines 56-63). Thus, Tennekoon teaches away from using neural stem cells. Tennekoon does not disclose or suggest a method of producing oligodendrocytes from mammalian multipotent *neural* stem cells, comprising contacting the neural stem cells with at least one oligodendrocyte promoting factor under conditions that result in production of oligodendrocytes from the multipotent neural stem cells. Therefore, claims 1-2, 5, 12-15 and 17-18 are not anticipated by Tennekoon and Applicants respectfully request withdrawal of this rejection.

Claims 1-2, 6, 9, 12, 14-15 and 17-28 were rejected under 35 U.S.C. § 102(b) for allegedly being anticipated by Mehler et al., Int. J. Devl. Neuroscience 13:213-240 (1995) ("Mehler").

Mehler does not disclose each and every element of the claims. Claim 1, the only rejected independent claim, defines a method of producing oligodendrocytes from mammalian multipotent neural stem cells, comprising contacting multipotent neural stem cells with an effective amount of at least one oligodendrocyte promoting factor under conditions that result in production of oligodendrocytes from the multipotent neural stem cells, wherein the oligodendrocyte promoting factor is selected from the group consisting of granulocyte-macrophage colony stimulating factor (GM-CSF), granulocyte colony stimulating factor (G-CSF), interleukin 3 (IL-3) and interleukin 5 (IL-5).

The cited passages of Mehler do not disclose or suggest providing G-CSF under conditions that result in production of oligodendrocytes from multipotent neural stem cells. Mehler states on page 230, 4th paragraph, that "[a]pplication of NT3, IGF1 and gp130-associated factors, either *individually* or in combination, did *not* potentiate expression of any OL lineage species. However, pretreatment or simultaneous application of bFGF or PDGF-AA, alone or in combination, followed by tandem application of NT3, IGF1 and an individual gp130-related factor resulted in...maturation of OL [oligodendrocyte] species generated from the initial neural stem cell population." Therefore, it is impossible to determine whether G-CSF had any effect on neural stem cells based on the cited passages of Mehler. Assuming *arguendo* that when Mehler states "gp130-associated factors" this includes G-CSF, then Mehler teaches away from the claims of the present application by stating that G-CSF alone or in combination does not promote oligodendrocyte production from neural stem cells. In contrast, as shown in Figure 1 of the present application, a colony stimulating factor (GM-CSF) was provided to neural stem cells under conditions that promote production of oligodendrocytes. Therefore, it is only the present application that provides one of skill in the art with a method of producing oligodendrocytes from mammalian multipotent neural stem cells, comprising contacting the neural stem cells with at least one oligodendrocyte promoting factor under conditions that result in production of

oligodendrocytes from the multipotent neural stem cells. Therefore, Mehler does not anticipate claims 1-2, 6, 9, 12, 14-15 and 17-18 and Applicants respectfully request withdrawal of this rejection.

Claims 1-3 and 5-15 were rejected under 35 U.S.C. § 102(e) for allegedly being anticipated by U.S. Patent No. 6,897,060 to Bjornson et al., ("Bjornson").

Bjornson describes a method of generating cells of the *hematopoietic* system from multipotent neural stem cells. Oligodendrocytes are not cells of the hematopoietic system. The cited passages of Bjornson state that GM-CSF and G-CSF are *hematopoietic* growth factors and can be used to generate cells of the hematopoietic system. The cited passages of Bjornson do not disclose or suggest oligodendrocyte promoting factors. The cited passages of Bjornson do not disclose that GM-CSF or G-CSF can be used to produce oligodendrocytes from multipotent neural stem cells. As discussed above, a reference that fails to disclose even one limitation will not be found to anticipate, even if the missing limitation could be discoverable through further experimentation. Furthermore, Bjornson is not enabling because Bjornson does not provide G-CSF or GM-CSF under conditions that result in production of oligodendrocytes from multipotent neural stem cells. Therefore, claims 1-3 and 5-15 are not anticipated by Bjornson and Applicants respectfully request withdrawal of this rejection.

35 U.S.C. § 103

Claims 1 and 16 were rejected for allegedly being obvious over Tennekoon in view of U.S. Patent Publication No. 2003/0171269 by Magil et al., ("Magil").

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art and *not* based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

Claims 1 and 16 are not obvious based on Tennekoon in view of Magil at least because the cited portions of the references alone or in combination fail to recite each and every element of the claims. As discussed above, Tennekoon's mesenchymal stromal cells are not and do *not* include neural stem cells. Therefore, Tennekoon does not disclose or suggest the methods defined by claims 1 and 16. Magil does not make up for the deficiencies of Tennekoon since Magil was only cited for describing EGF51N. The cited portions of Tennekoon and Magil alone or in combination fail to disclose or suggest that EGF51N is a biological agent that can increase neural stem cells numbers.

The cited references also do not provide one of ordinary skill in the art with a reasonable expectation of success. Tennekoon states that neural stem cells have drawbacks and are difficult to obtain (see column 1, lines 56-63). Therefore, Tennekoon teaches away from using neural stem cells. Therefore, claims 1 and 16 are not obvious based on Tennekoon in view of Magil, and Applicants respectfully request withdrawal of this rejection.

It is believed that no fee is due at this time. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

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